

Reference will be made herein to each of these five declarations.¹

Claims 1-36 remain in this application, and are presented for reconsideration.

II. CLAIM FOR PRIORITY UNDER 35 U.S.C. § 120

With the Amendment filed March 25, 1994, Applicants amended the specification to indicate that the present application is a continuation-in-part application of application Serial No. 07/313,919, filed February 23, 1989, now abandoned.²

In the subject Office Action, the Examiner requests an explanation of why the first filed application was not earlier identified.

As explained in the remarks appended to the Amendment filed March 25, 1994, the present application includes substantial disclosure in addition to that included in the originally filed application, and the broadest claims in the present application are directed to some of this additional subject matter.

¹ Citations to the five declarations will include the name of the declarant, followed by a paragraph number. For example, citations to Dr. Shepherd's declaration will take the form "Shepherd, ¶ ____."

² 35 U.S.C. § 120 expressly permits an application to claim the benefit of the filing date of an earlier application if the second application is filed before the "patenting or abandonment of or termination of proceedings on the first application," and if the second application "contains or is amended to contain a specific reference to the earlier filed application," (emphasis added).

For example, the present application includes 11 figures, only two of which (Figures 1 and 6) appear in the originally filed application. Figure 1 of the present application presents known extinction coefficients for several hemoglobin species, and Figure 6 presents the hardware environment within which the present invention functions. It is noted that each of the presently pending claims are method claims, that do not rely on any particular hardware environment.

It is the functions presented in the present application that are the most important, and the broadest claims pending in this application recite functions that are nowhere suggested in application Serial No. 07/313,919.

For example, sole independent claim 1 requires the generation of a plurality of radiation wavelengths, including an absorbance subset of wavelengths, and a scattering subset of wavelengths. The claim also requires that the absorbance subset of wavelengths has been selected to minimize the effects of radiation scattering and to maximize radiation absorbance by constituent components of unaltered whole blood, the concentrations of which are to be determined. In addition, the claim requires that the scattering subset of wavelengths has been selected to maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance.

Sole independent claim 1 also requires that the concentrations of the constituent components, corrected for the

effects of scattering, are calculated as functions of detected intensities of radiation at each of the radiation wavelengths of the absorbance subset and the scattering subset.

The concepts of generating a scattering subset of wavelengths, and the use of detected intensities of radiation in the scattering and absorbance subsets to calculate corrected concentrations of constituent components (each of which are important to the presently claimed invention), are nowhere contemplated by the disclosure or claims in application Serial No. 07/313,919.

It is also noted that several of the concepts recited in the dependent claims pending in this application find absolutely no basis or suggestion in the parent application. For example, there is no basis or suggestion for the correction of the calculated concentrations of the constituent components for the effects of the finite spectral bandwidth of the substantially monochromatic wavelengths (claim 10); for the selection of radiation wavelengths through use of a computed error index (claims 11 and 29 and dependent claims 12-19 and 30-33); for the correction of the calculated concentrations of the constituent components for the effects of light scattering by red blood cells, and/or nonspecific light scattering (claims 20, 23 and 26); for performing scattering correction as a function of the relative concentrations of the constituent components (claims 21, 24 and 27); for performing scattering correction as a function of wavelength (claims 34, 35 and 36); or for the iterative

determination of a red blood cell scattering vector and/or nonspecific scattering vector (claims 22, 25 and 28).

For this reason, claiming priority under 35 U.S.C. § 120 may not have been appropriate. However, as explained in the remarks appended to the Amendment filed March 25, 1994, the identification of application Serial No. 07/313,919 was done simply to bring to the attention of the Patent Office the existence of the prior application.³

It is noted that all of the prior art cited in application Serial No. 07/313,919 was filed by Applicants in the present application and is of record. In addition, since 35 U.S.C. § 120 expressly contemplates amending an application to refer to an earlier filed application (see footnote 2, above), what Applicants have done is permitted by the statute.

In any event, the earlier filed application has been brought to the attention of the Examiner by Applicants and is now of record in this case. In addition, all of the prior art cited in that application is of record in this case. Thus, anything within Applicants' knowledge that could possibly be considered material to the examination of this application has been identified by Applicants and is before the Patent Office, and Applicants respectfully contend that they have fully and

³ As noted in the Remarks appended to the Amendment filed March 25, 1994, at that time, claiming priority under 35 U.S.C. § 120 did not eliminate any applied prior arts. As explained in more detail in Section IV. A., this is no longer the case.

completely complied with the letter and intent of 37 C.F.R.
§ 1.56.

**III. THE REJECTION OF CLAIMS BASED ON ANDERSON ET AL.
UNDER 35 U.S.C. §§ 102(b) AND 103**

The Examiner rejects claims 1, 10, 20-24, 26-27 and 34-36 under 35 U.S.C. § 102(b) as being anticipated by Anderson et al. In addition, the Examiner rejects claims 2-9, 11-19, 25 and 28-33 under 35 U.S.C. § 103 as being obvious in view of Anderson et al. In light of the following discussion, Applicants respectfully traverse each of these rejections.

A. Anderson et al. Use Altered Blood

Sole independent claim 1 of the present application requires the determination of "concentrations of a plurality of constituent components of unaltered whole blood of unknown composition," (emphasis added). The Examiner believes that Anderson et al. performed measurements of unaltered whole blood of unknown composition (Office Action at page 4). Such is not the case.

The second paragraph on page 177 of Anderson et al. states (with added emphasis): " Fully oxygenated nonhaemolysed red cells suspended in isotonic saline were studied. . . ."

Before suspending nonhemolyzed red blood cells in isotonic saline, Anderson et al. must first separate the red blood cells from the other components of whole blood, thus altering the blood sample. This effectively eliminates many of the contributors to light scattering mentioned in the third paragraph on page 7 of

the present application, and discussed below in detail in Section III. B. 1. Moreover, by using "fully oxygenated" red cells, the samples used by Anderson et al. are of known composition, i.e., oxyhemoglobin (also referred to as HbO₂ in the present application). No other hemoglobin species (deoxy-, carboxy-, met- or sulfhemoglobin), are present in the samples measured by Anderson et al.

Therefore, contrary to the Examiner's interpretation of Anderson et al., Anderson et al. measure altered whole blood of known composition (Pittman, ¶ 11; Schmitt, ¶ 11; Nilsson, ¶ 16; Öberg, ¶ 16).

B. Anderson et al. Do Not Contemplate Calculating Corrected Concentrations Using An Absorbance Subset And A Scattering Subset Of Radiation Wavelengths

Sole independent claim 1 of the present application requires the generation of a plurality of radiation wavelengths, the plurality of wavelengths including an absorbance subset that has been selected by their ability to distinguish the constituent components of unaltered whole blood of unknown composition, and having been selected to minimize the effects of radiation scattering and to maximize radiation absorbance by these constituent components. The plurality of wavelengths also includes a scattering subset of wavelengths that have been selected to maximize the effects of scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood.

Claim 1 also requires the calculation of the concentrations of the plurality of constituent components of the sample of unaltered whole blood, corrected for the effects of radiation scattering, as a function of detected intensities of the radiation wavelengths of the absorbance subset and of the scattering subset, after passing through the sample. Dependent claims 20-36 expand on the details of correction for the effects of radiation scattering.

The Examiner relies on the first paragraph from page 180 of Anderson *et al.* for the proposition that Anderson *et al.* allegedly contemplate correction for scattering (Office Action at page 4).

Applicants believe this conclusion by Anderson *et al.* to be fundamentally incorrect, and believe that it may have misled the Examiner to thinking that Anderson *et al.* can accurately deduce the magnitude of light scattering produced by an unknown sample of whole blood from measured optical density values and known extinction coefficients of the hemoglobin species under consideration.

The relevant statement on page 180 of Anderson *et al.* shows that at least four key features of the presently claimed invention were completely unknown to Anderson *et al.* Specifically, the statement is completely false since it does not account for:

- the sample-to-sample variation in light scattering in whole blood due to the eight

factors described on page 7, paragraph 3 of the present application; or

- the hemoglobin species-dependence of the scattering vectors described on page 7, paragraph 2 of the present application; or
- the wavelength dependence of the scattering vectors described on page 7, paragraph 1 of the present application; or
- the fact that there are actually at least two independent scattering vectors to be found when whole blood is illuminated, as described on pages 20-30 of the present application.

In accordance with the presently claimed invention, it is the generation of the scattering subset of wavelengths, in addition to the absorbance subset of wavelengths, that permits the presently claimed invention to correct for errors introduced in the determination of the concentrations of the constituent components of unaltered whole blood of unknown composition. Such correction is nowhere contemplated by Anderson et al., as explained in more detail in the following subsections.

1. **Light scattering in unaltered whole blood samples is unpredictable from one sample to another.**

As mentioned in the third paragraph on page 7 of the present application, there are at least eight uncontrolled factors identified that make light scattering in whole blood samples unpredictable from one sample to another. These are: 1) the

different plasma protein concentrations that determine the refractive index of plasma in one sample versus another; 2) the aggregation of red blood cells in the sample; 3) the different hemoglobin concentrations inside the red cells that alter their refractive index; 4) the size and shape of the red blood cells; 5) chylomicrons or other light-scattering lipid particles; 6) cell fragments; 7) microscopic clots; and 8) light-sieving effects of sedimented red blood cells, (Schmitt, ¶¶ 10, 12, 14; Pittman, ¶¶ 10, 12, 14; Öberg, ¶ 11; Nilsson, ¶ 11).

In trying to back-calculate hemoglobin concentrations from measured optical densities of whole blood for an unknown sample of whole blood, one cannot first adjust the parameters in Twersky's equation (the equation used by Anderson *et al.*) to fit the data and then turn around and subtract off the scattering term to determine the part due to absorbance by hemoglobin, yet this is what would have to be done even to attempt to apply Twersky's theory in the manner suggested by the Examiner, (Schmitt, ¶ 9; Pittman, ¶ 9; Nilsson, ¶ 12; Öberg, ¶ 12). Furthermore, the Twersky formalism used by Anderson *et al.* describes "ideal" whole blood, and does not even include provisions for dealing with red cell aggregation, chylomicrons, cell fragments, and other uncontrolled factors that cause light scattering in real whole blood samples, (Schmitt, ¶ 10; Pittman, ¶ 10; Nilsson, ¶ 11; Öberg, ¶ 11). Moreover, as mentioned above in Section III. A., Anderson *et al.* perform measurements on

"ideal" whole blood in the form of oxygenated red cells suspended in isotonic saline.

2. Light scattering in unaltered whole blood samples depends in a complicated way on the particular hemoglobin species present in the sample under consideration.

In the second paragraph on page 7 of the present application, it is pointed out that the total contribution to the optical absorbance of whole blood due to light scattering depends in a complicated way on the actual hemoglobin species present in the sample under consideration. For example, the sample may be comprised purely of oxyhemoglobin or 50% oxyhemoglobin and 50% carboxyhemoglobin, or the sample may be comprised of any combination of the possible hemoglobin species. A naive reading of Anderson *et al.* (namely that the contribution to unaltered whole blood's optical absorbance which is due only to light scattering is determined by path length, total hemoglobin concentration, and detecting geometry) would not allow for the dependence of light scattering on the particular hemoglobin species present in the given sample.

The presently claimed invention, by generating a scattering subset in addition to an absorbance subset of wavelengths (claim 1), makes a quantitative correction for the light scattering of each unknown blood sample as a function of the particular hemoglobin species it contains (also see Figures 4 and 5 of the present application, and supporting text). This correction is expressly included in claims 21, 24 and 27 (and claims 22, 25 and 28-33 dependent therefrom). The passage cited by the Examiner

from page 180 of Anderson et al. demonstrates that Anderson et al. were completely unaware of the necessity of having a hemoglobin-species-dependent scattering vector.

3. Light scattering in unaltered whole blood depends in a complicated way on the wavelength of the impinging light.

In the first paragraph on page 7 of the present application, it is pointed out that the total contribution to the optical absorbance of whole blood due to light scattering depends in a complicated way on the wavelength of the impinging light. In the passage cited by the Examiner from page 180 of Anderson et al., it is stated that "scattering remains the same for this sample depth and haemoglobin content when wavelength is varied." This assertion is patently false as the data of Pittman clearly shows (Figure 3 of the present application; Nilsson, ¶ 11; Öberg, ¶ 11). In contrast to this misconception of Anderson et al., the present invention makes a quantitative correction for the light scattering of each unknown blood sample (claim 1), specifically by employing scattering vectors that vary with wavelength (claims 34, 35 and 36). The passage cited by the Examiner demonstrates that Anderson et al. were completely unaware of the necessity or utility of using wavelength-dependent scattering vectors.

4. There are actually at least two independent scattering vectors to be found when whole unaltered blood is illuminated.

Pages 20-30 of the present application describe both a red blood cell scattering vector and a nonspecific scattering vector. Claims 20, 23 and 26 (and claims 21, 22, 24, 25 and 27-36

dependent therefrom) are specifically directed to these features. Both vectors are important in making accurate measurements of the concentrations of hemoglobin species in unaltered whole blood. There is no hint of two or more forms of scattering in Anderson et al., or in Twersky's theory used by Anderson et al. Therefore, the innovation of these two independent scattering vectors as disclosed and claimed in the present application is original and could not have been deduced from Anderson et al.

5. Summary of errors and misconceptions in Anderson et al.

Anderson et al. do not apply Twersky's theory to whole blood in such a way as to account for any of the four factors listed in subsections 1.-4. above. These factors show conclusively that Anderson et al.'s use of Twersky's theory failed to provide or even suggest a method for measurement of oxy-, deoxy-, carboxy-, met- and sulfhemoglobin in unaltered whole blood of unknown composition.

In rejecting claims 1, 10, 20-24, 26-27 and 34-36 under 35 U.S.C. § 102(b) as anticipated by Anderson et al., the Examiner asserts that "Anderson inherently has correction" for light scattering (Office Action at page 4). The foregoing discussion demonstrates that the only "correction" that Anderson et al. have is merely a fixed quantity that fails to take into account the eight or more uncontrolled factors that make the magnitude of light scattering unpredictable from one sample of whole blood to the next, that fails to contemplate a scattering subset of wavelengths to accommodate these uncontrolled factors (claim 1),

that fails to treat the wavelength-dependence of the light scattering (claims 34, 35 and 36), that does not account for the variation of the magnitude of light scattering from one blood sample to another (claims 22 and 25), that does not account for the dependence of the magnitude of light scattering on the particular hemoglobin species present in the sample (claims 21, 22, 24, 25 and 27-33), and that does not include either of the scattering vectors of the presently claimed invention (claims 20-36). For this reason alone, Applicants respectfully request the Examiner to withdraw the rejection of claims 1, 10, 20-24, 26-27 and 34-36 as being anticipated by Anderson et al.

C. Anderson et al. Do Not Render Claims 2-9, 11-19, 25 and 28-33 Obvious

On pages 5 and 6 of the subject Office Action, the Examiner states that it would be obvious to modify Anderson et al. to supply:

the specific depth of the sample, the specific detecting area, the specific distance from the sample, the specific half aperture angle of radiation emanating from the sample, computing an error index, selecting a wavelength range for bilirubin or sulfhemoglobin, red blood cell scattering vector and non specific scattering vector.

The Examiner continues by characterizing these features as "a matter of design engineering," and by stating that "a specific relationship between all of these specifics cited above are [sic] well known," (Office Action at page 6). Applicants respectfully traverse this rejection.

After intensive review of the Anderson et al. disclosure (and other prior art known to Applicants), Applicants cannot find

the purported "well-known" relationships. Further, Applicants have filed the declarations of experts that state they cannot find these relationships either, (Öberg, ¶ 9; Nilsson, ¶ 9). Thus, it is apparent that the Examiner's assertions on pages 5 and 6 of the subject Office Action are based on facts within her personal knowledge. Therefore, as provided by 37 C.F.R. § 1.107(b), Applicants respectfully request that the Examiner prepare an affidavit to substantiate the assertions stated on pages 5 and 6 of the subject Office Action.

Specifically, pursuant to 37 C.F.R. § 1.107(b), Applicants request the Examiner to specify the following elements that appear nowhere in the disclosure of Anderson *et al.*, and that the Examiner contends are "well-known" and a matter of "design engineering":

1. determination of detecting area (claims 4 and 5);
2. determination of distance between detector and sample (claims 6 and 7);
3. determination of aperture half-angle (claims 8 and 9);
4. the selection of radiation wavelengths having minimum calculated error indices (claims 11 and 29, and claims 12-19 and 30-33 dependent therefrom); and
5. the determination of a red blood cell scattering vector, and the determination of a nonspecific scattering vector (claims 22, 25 and 28, and claims 29-33 dependent therefrom).

Applicants respectfully assert that absent some clear teaching in the prior art, or absent personal knowledge of the Examiner, the above-detailed features are nowhere disclosed or suggested in the Anderson *et al.* reference, and are not "well-known" as contended by the Examiner.

For this reason, Applicants respectfully request the Examiner to withdraw the rejection of claims 2-9, 11-19, 25 and 28-33 under 35 U.S.C. § 103 as being unpatentable over Anderson *et al.*

In addition, while Applicants do not believe that a *prima facie* case of obviousness has been established, Applicants respectfully assert that the secondary considerations, presented in the Declaration of Dr. A. P. Shepherd and discussed below in detail in Section IV, would rebut any such *prima facie* case.

**IV. REJECTION OF CLAIMS BASED ON CURTIS
UNDER 35 U.S.C. §§ 102(a) AND 103**

The Examiner, for the first time, rejects claims based upon the Curtis reference, U. S. Patent No. 5,064,282. Specifically, claims 1, 10, 20-21, 23-24, 26-27 and 34-36 stand rejected under 35 U.S.C. § 102(a), and claims 11-19 and 29-33 stand rejected under 35 U.S.C. § 103. In light of the following comments, Applicants respectfully traverse this rejection.

A. Curtis Is Not Prior Art

Curtis was filed September 26, 1989, and issued November 12, 1991. The present application is a continuation-in-part of application Serial No. 07/313,919, filed February 23, 1989. The

parent application discloses the generation of a plurality of wavelengths (parent application at page 6, lines 15-32),⁴ the irradiating of a blood sample (parent application at page 8, lines 28-30), the detecting of intensities of the radiation wavelengths after passing through the sample (parent application at page 5, lines 8-10 and page 8, lines 30-35), and the calculation of concentrations of components based upon the intensities and extinction coefficients (parent application at page 5, lines 10-14 and page 9, lines 13-17).⁵ Thus, the relevant teachings of the Curtis reference find support in the parent application; and the Curtis reference is not prior art under any section of 35 U.S.C. § 102 and, therefore, cannot be used as a reference under § 103. *See, e.g.,* 35 U.S.C. § 120; *State Industries, Inc. v. A. O. Smith Corp.*, 751 F.2d 1226, 1232-33 (Fed. Cir. 1985).

B. Curtis Uses Altered Blood

The Examiner states that Curtis is "an unaltered whole blood analysis system," (Office Action at page 7). However, this is not the case because Curtis hemolyzes the blood sample before measurement. Curtis states explicitly that prior hemolysis of

⁴ As noted above in Section II, the parent application does not contemplate the generation of a scattering subset of wavelengths in addition to an absorbance subset of wavelengths.

⁵ Once again, as stated above in Section II, the parent application does not contemplate calculating concentrations corrected for scattering as a function of detected intensities of both the absorbance subset and scattering subset of wavelengths.

the sample is a necessary and an essential step in his measurement method.

Specifically, Curtis, at column 2, line 4, states, "The only reagent required is a lysing agent which breaks up the erythrocytes to release the hemoglobin." Similarly, at column 5, line 45, Curtis states ". . . the only reagent required is saponin, a natural substance which acts as a lysing agent and breaks up the erythrocytes to release hemoglobin." (Öberg, ¶ 6; Nilsson, ¶ 6).

By contrast, the presently claimed invention makes multiple spectrophotometric measurements directly in "unaltered whole blood," without hemolysis or other conditioning (claim 1).

Although the Examiner concludes that "minimization of radiation scattering are [sic] disclosed by Curtis," (Office Action at page 7), it is clear from the disclosure of Curtis that Curtis does not disclose minimization of radiation scattering by any means other than hemolysis (Öberg, ¶ 8; Nilsson, ¶ 8). Moreover, because the method of Curtis requires hemolysis, Curtis gives no clues whatsoever as to how one would make meaningful measurements in the presence of the intense light scattering produced by unaltered whole blood -- measurements that only the presently claimed invention permits.

C. Curtis Does Not Disclose The Claimed Absorbance Subset And Scattering Subset Of Wavelengths For Unaltered Whole Blood

At pages 7-8 of the subject Office Action, the Examiner concludes that Curtis renders obvious the selection of radiation

wavelengths recited in claims 11-19 and 29-33. Applicants respectfully traverse this rejection.

Curtis selects two wavelengths for the purpose of measuring total hemoglobin concentration (Curtis, Abstract). However, contrary to the Examiner's conclusion, Curtis' method of selecting these wavelengths is completely different from that of the presently claimed invention.

Specifically, Curtis states:

Two absorbance measurements are made, the first at a wavelength at which the absorbance of oxyhemoglobin and deoxyhemoglobin are approximately equal, near an isobestic point, and a second measurement at which these components absorb substantially no light.

Curtis, Abstract, lines 8-13; also see column 4, lines 21-30; accord Öberg, ¶ 13; Nilsson, ¶ 13.

Thus, while Curtis contemplates selecting radiation wavelengths based upon absorbance criteria, there is absolutely no disclosure or suggestion in Curtis of selecting an absorbance subset of wavelengths "by their ability to distinguish the constituent components and . . . to minimize the effects of radiation scattering and to maximize radiation absorbance by said constituent components," as expressly required by sole independent claim 1. Further, there is absolutely no disclosure or suggestion in Curtis of a scattering subset of wavelengths of any kind, much less a scattering subset of wavelengths that have been "selected to maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood," also as required by sole

independent claim 1. For this reason alone, dependent claims 11-19 and 29-33 should not be considered obvious in light of the teachings of Curtis.

In addition, there is absolutely no disclosure or suggestion of the selection of radiation wavelengths based on the minimization of error indices that have been computed as the sum of the absolute values of the errors that are introduced in the measurement of relative concentrations of HbO₂, HbCO and Hi due to a change in optical density measurements, as expressly required by dependent claims 11 and 29, and claims dependent therefrom (Öberg, ¶ 14; Nilsson, ¶ 14).

v. SECONDARY CONSIDERATIONS

Filed herewith is the Declaration Under 37 C.F.R. § 1.132 of Dr. A. P. Shepherd, attesting to the commercial success of the presently claimed invention.

Specifically, Dr. Shepherd's company, A-VOX Systems, Inc., manufactures and sells an oximeter known as the AVOXimeter 1000, that incorporates the presently claimed invention (Shepherd, ¶¶ 3, 4).

Without the aid of distributors and using only direct mail solicitation, A-VOX Systems, Inc. sold 34 AVOXimeter 1000's in 1993, resulting in cash receivables totaling \$261,513 (Shepherd, ¶ 5). In addition, in the first nine months of 1994, A-VOX Systems, Inc. has sold approximately 67 AVOXimeter 1000's, resulting in accounts receivable of \$537,680 (Shepherd, ¶ 6).

Thus, the first nine months of 1994 represent more than a 100% increase over the cash receivables for the entire year of 1993 (*Id.*).

In addition, A-VOX Systems, Inc. has received an offer from Instrumentation Laboratory Company to license the technology disclosed and claimed in the present application (Shepherd, ¶ 7). Although no formal license agreement has been reached to date, royalty rates on the order of 5% to 6% of the incremental value added by the licensed technology are presently contemplated by both parties. At present, this converts to a payment of between \$250 and \$300 per unit sold by Instrumentation Laboratory Company (Shepherd, ¶ 7).

Such evidence of secondary considerations has great utility in an obviousness determination, *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), and in fact "requires a finding of nonobviousness if the matter be otherwise doubtful," *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (nonobviousness shown from license of patent not yet issued).

In addition, when *prima facie* obviousness is established⁶ and evidence is submitted in rebuttal, the Examiner must start over. Facts established by rebuttal evidence must be evaluated along with facts on which the earlier conclusion of obviousness was reached, not against the conclusion itself. In other words, it is error to review rebuttal evidence solely on its "knock down

⁶ As mentioned above in Sections III. C. and IV., Applicants vigorously assert that a *prima facie* case of obviousness has not been established.

ability." *In re Piasecki*, 745 F.2d 1468, 1472-73 (Fed. Cir. 1984); *In re Rinehart*, 531 F.2d 1048, 1052 (C.C.P.A. 1976).

The required nexus exists between the commercialization of the present invention and the claims because at least claim 1 of the present application covers the entire AVOXimeter 1000. In such a situation, "prima facie evidence of nexus is established if there was commercial success and if the invention disclosed in the patent was that which was commercially successful." *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991); see also, *Demaco Corp. v. F. Von Langsdorff Licensing Co. Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988).

In addition, although Dr. Shepherd's affidavit does not set forth the overall market for oximeters, or the specific percentage of penetration of the sales of the invention into that market, it is eminently clear that there are the beginnings of significant sales of the invention (approximately 101 in 21 months, resulting in almost \$800,000 in receivables) without distributors and using only direct-mail advertising (Shepherd, ¶¶ 5, 6). In addition, sales are on a rather dramatic increase; the sales for the first nine months of 1994 increasing over 100% of the entirety of the sales of 1993 (Id.). These numbers and their dramatic increase over a very short period of time are indicative of the beginnings of a "'rush to the invention' [that is] probative of nonobviousness." *Nickola v. Peterson*, 580 F.2d 898,

914 (6th Cir. 1978) (opinion by Judge Markey, then Chief Judge of the C.C.P.A.).

Applicants respectfully assert that this evidence of commercial success is sufficient to overcome a *prima facie* case of obviousness, if in the opinion of the Examiner one has been established.

VI. REJECTION OF CLAIMS BASED ON RES JUDICATA

Claims 1, 2, 5, 6, 9-21, 23-24, 26-27, and 29-36 were rejected under res judicata on the basis of an earlier adverse decision of the Board of Appeals in application Serial No. 07/313,919. However, the res judicata doctrine is not appropriate because Rule 197(c) establishes the right to file a continuation application following an adverse Board decision within time allowed for further appeal, and to have that application examined⁷. *In re Kaghan*, 387 F.2d 398, (C.C.P.A. 1967). The *Kaghan* court stated:

MPEP section 201.07 allows an applicant to file a continuation application and so establish a right to further examination by the examiner. Such continuation applications can be filed at any time before the "termination of proceedings on the first application." 35 U.S.C. § 120. Following a Board of Appeals decision, proceedings are considered terminated "when the time for appeal to the court or review by civil action has expired and no such appeal or civil action

⁷ The present application was filed on September 29, 1992, within the time for appealing the Board's decision in the parent application to the Federal Circuit.

has been filed." Rule 197(c).⁸ We interpret these passages as establishing the right of an applicant to file a continuation application following an adverse Board of Appeals decision within the time allowed for further appeal, and as establishing his right to have that application examined. A holding of res judicata without reliance on any other ground of rejection is not an examination on the merits of the application and so may not be used in such a situation.

In re Kaghan is consistent with MPEP 706.03(w) which instructs the examiner not to use res judicata unless "the earlier decision was a decision of the Board of Appeals or any one of the reviewing courts and when there is no opportunity for further court review of the earlier decision." *In re Kaghan* has been followed by *Plastic Contact Lens Co. v. Commissioner*, 484 F.2d 837, 179 U.S.P.Q. 263-64 (D.C. Cir. 1973).

Furthermore, even if the res judicata doctrine were somehow applicable to the claims in question, the claims would not be properly rejected under the doctrine because the claims in question are distinguishable from the claims of application Serial No. 07/313,919 which were subject to the Board's decision.

For example, claim 1 of the present application is distinguishable from the corresponding claim 1 of application Serial No. 07/313,919. Claim 1 presently under examination requires the step of generating a plurality of radiation wavelengths, including an absorbance subset of wavelengths that have been selected by their ability to distinguish the

⁸ The applicable section of Rule 197(c) now reads: "The date of termination of proceedings is the date on which the appeal is dismissed or the date on which the time of appeal to the court or review by civil action (§ 1.304) expires."

constituent components and to minimize the effects of radiation scattering and to maximize radiation absorbance by the constituent components. Also included among the plurality of generated wavelengths is a scattering subset of wavelengths that have been selected to maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood. Claim 1 presently under examination also requires the calculation of concentrations of the plurality of constituent components, corrected for the effects of radiation scattering, based upon detected intensities of each of the plurality of wavelengths, including each of the absorbance subset of wavelengths and scattering subset of wavelengths.

In contrast, the claims on appeal in application Serial No. 07/313,919 required only the generation of a plurality of radiation wavelengths, without requiring a subset of those wavelengths to be a scattering subset of wavelengths, selected according to specified criteria. In addition, claim 1 on appeal in Serial No. 07/313,919 did not calculate concentrations of the constituent components as a function of the scattering subset of wavelengths.

To further emphasize the distinctions between claim 1 presently under examination, and claim on appeal in application Serial No. 07/313,919, Applicants present, in tabular form, the first and last elements of each claim.

FIRST AND LAST ELEMENTS OF CLAIM 1 UNDER EXAMINATION	FIRST AND LAST ELEMENTS OF CLAIM 1 ON APPEAL IN SERIAL No. 07/313,919
<p>generating a plurality of substantially monochromatic radiation wavelengths, each wavelength of an absorbance subset of said plurality of wavelengths having been selected by their ability to distinguish the constituent components and having been selected to minimize the effects of radiation scattering and to maximize radiation absorbance by said constituent components, and each wavelength of a scattering subset of said plurality of wavelengths having been selected to maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood;</p>	<p>generating a plurality of radiation frequencies each determined to distinguish one said constituent component from another said constituent component, and to minimize the effect of radiation scattering and to maximize radiation absorbance by whole, undiluted blood;</p>
<p>calculating concentrations of said plurality of constituent components of said sample of unaltered whole blood corrected for the effects of radiation scattering, based upon detected intensities of each of said plurality of radiation wavelengths, and based upon predetermined molar extinction coefficients for each of said constituent components at each of said plurality of radiation wavelengths.</p>	<p>calculating concentrations of each of at least three said constituent components of said sample of whole, undiluted blood, based upon detected intensities of said radiation frequencies, and upon predetermined molar extinction coefficients for each of said constituent components at each of said radiation frequencies.</p>

As the Supreme Court stated in *Commissioner of Internal Revenue v. Sunnen*, 333 U.S. 591, 597-98 (1948):

It is first necessary to understand something of the recognized meaning and scope of res judicata, a doctrine judicial in origin. The general rule of res judicata applies to repetitious suits involving the same cause of action. It rests upon considerations of economy of judicial time and public policy favoring the establishment of certainty in legal relations.

Where, as here, the claims in a parent file and a CIP application are different, the "considerations of economy of judicial time and public policy favoring the establishment of certainty" are not being furthered, and hence, res judicata is not appropriate.

In re Fried, 312 F.2d 930 (C.C.P.A. 1963).

In re Fried involved a CIP application filed after an unappealed finding by the Board that the claims in the parent file were not patentable under 35 U.S.C. § 112. The Applicants added a limitation in the CIP claims that was not present in the parent. The examiner rejected the CIP claims under res judicata, and the Board affirmed. The C.C.P.A., in reversing the Board properly noted that "[s]ince different claims are here presented the issues decided in the parent application and those to be here decided are not the same." *Id.* at 931. The C.C.P.A. went so far as to state, "[t]he present case provides cogent support for the requirement that the issues must be identical before res judicata is applicable." *Id.* at 932, n.3 (emphasis added).

The facts in the present action are very similar to those set forth in *In re Fried*. Both involve the same procedural posturing (i.e., unappealed Board affirmations of final rejections). Both involve CIP claims containing a limitation not found in the parent claims.

The additional limitation of a scattering subset of wavelengths, selected according to specified criteria, is enough to preclude the application of res judicata based on the Board's treatment of the claims of the parent application. Applicants